

510(K) SUMMARY

[as required by 807.92(c)]

JAN 13 2012

A. 510k Number:**B. Applicant:**

Company name: PATS CORP

Address: 205 S Broadway, Suite 718, Los Angeles California 90012 USA

Contact person: Daniel Nam

Phone: 213-626-1544

C. Proprietary and Established Names: DAESUNG MAREF CO LTD

Address: 689-31 Gumjung-dong, Gunpo-si Gyeonggi-do 451-864 KOREA

D. Regulatory Information

Regulation Number: 21 CFR 870.5800

Regulation Name: Compressible Limb Sleeve

Regulatory Class: Class II

Product Code: JOW

Proprietary Name: The Venous Assist System DVT-2600

E. Intended Use

DVT-2600 is a system to prevent DVT (Deep Vein Thrombosis) by improving the blood velocity of patients. DVT-2600 is Circulation Enhancement, Deep Vein Thrombosis Prophylaxis, Edema – Acute, Edema – Chronic, Extremity Pain Incident to Trauma or Surgery Leg Ulcers, Venous Stasis / Venous Insufficiency

F. Device Description

DVT-2600 device is a specialized intermittent pneumatic compression (IPC) system to prevent DVT (Deep Vein Thrombosis) and PE (Pulmonary Embolism) by improving the venous blood flow in at risk patients. The system consists of the controller, the tubing sets and 3 types(Non-woven, Fabric, Oxford) garments. The system offers Sequential inflation promoting venous blood movement and metabolism and then has sufficient interval time to refill with blood sufficiently after deflation. The operation of the inflation and deflation is repeated until the stop button is activated.

We recommend using the device separately or with anti-coagulant materials or compression stocking to help prevent DVT and PE under a doctor's consultant.

G. Substantial Equivalence Information

Predicate Device 1

- 510(k) number: K040511
- Name: SCD Express"4 system
- Classification: 2

1. Comparison with predicate

The Venous Assist System DVT-2600 has substantial equivalent intended use as the-market-cleared SCD Express"4 system and has substantial equivalent technological and performance characteristics with SCD Express"4 system. After analyzing both bench as well as laboratory testing to applicable standards, it is the conclusion of The Venous Assist System DVT-2600 is as safe and effective as the predicate devices, has few technological differences, but there are no new indications for use and without raising any new safety and/or effectiveness concerns.

Consequently, it is clear that it substantially equivalent to the predicate devices.

H. Performance Characteristics (If/when applicable)

- Council Directive 93/42/EEC of 14 June 1993 concerning medical devices
- IEC 980:2003, Graphical symbols for use in the labeling of medical devices
- IEC1041:1998, Information supplied by the manufacturer with medical devices
- ISO 13485:2003, Medical devices - Quality management systems - Requirements for regulatory purposes
- ISO 14155-1:2003, Clinical investigation of medical devices for human subjects - Part 1: General requirements
- ISO 14971:2007, Medical devices - Application of risk management to medical devices
- IEC 60601-1, Medical electrical equipment - Part 1: General requirements for safety (IEC 60601-1:1988/A1:91/A2:95)
- IEC 60601-1-2, Medical electrical equipment - Part 1: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

DAESUNG MAREF CO., LTD.
c/o Mr. Daniel Nam
General Manager PATS CORP.
4568 West 1st Street, Suite 104
Los Angeles, CA 90004

JAN 13 2012

Re: K112677

Trade/Device Name: The Venous Assist System DVT-2600
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: January 3, 2012
Received: January 9, 2012

Dear Mr. Nam:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K112677

Indications for Use

510(k) Number (if known): K112677

Device Name: The Venous Assist System DVT-2600

Indications For Use: DVT-2600 is a system to prevent DVT (Deep Vein Thrombosis) by improving the blood velocity of patients. DVT-2600 is Circulation Enhancement, Deep Vein Thrombosis Prophylaxis, Edema – Acute, Edema – Chronic, Extremity Pain Incident to Trauma or Surgery, Leg Ulcers, Venous Stasis / Venous Insufficiency.


Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K112677